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PATENT AND TECHNICAL TRANSLATION

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DECLARATION

The undersigned, Olaf Bexhoeft, hereby states that he is well acquainted with both the English and German languages and that the attached is a true translation to the best of his knowledge and ability of the German text of PCT/EP2004/010725, filed 09/24/2004, and published on 04/07/2005 as WO 2005/030050 A1.

The undersigned further declares that the above statement is true; and further, that this statement was made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any patent resulting therefrom.

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Blood Pressure Measuring Method and Blood Pressure Manometer

The invention relates to a blood pressure measuring method, wherein a pulse oscillogram of a patient is determined and from this the blood pressure is detected and displayed, as well as to a sphygmomanometer for executing the method.

Such a non-invasively measuring blood pressure measuring method, or sphygmomanometer, is disclosed in EP 1 101 440 A1. With this known method, or device, which is based on an oscillometrically-measuring, automatic method, one or several pulse oscillograms are selectively generated in the course of a blood pressure measuring operation, in order to determine the blood pressure values from it or them, and to display them. In the first mode of operation, a systolic and a diastolic blood pressure value are determined in a manner customary per se in one measurement cycle by means of a single pulse oscillogram, while in the second mode of operation it is inter alia determined on the basis of several definite pulse oscillograms, between which a pause of 60 sec. is maintained, whether so-called hemodynamic stability exists. If there is no hemodynamic stability, this is indicated to the user by the output of an error code. Thus the user is informed in this way when the measured

blood pressure values have been adulterated because of insufficient hemodynamic stability, in particular insufficient circulatory rest wherein, however, the measuring time is not inconsiderably increased.

A method or device represented in DE 102 18 754 A1 for measuring blood pressure is additionally designed for detecting arrhythmia, wherein pulse wave information, such as the width, height and a time interval is detected for a plurality of beats. However, with a lack of circulatory rest, the blood pressure values per se cannot not be sufficiently accurately measured.

The lack of circulatory rest is considered to be the most important error influence in the course of an outpatient measurement of arterial blood pressure. Patients doing their own measuring, but even medical specialists, do not possess criteria which are simple to detect during blood pressure measurements in order to judge circulatory rest. In many cases the length and size of a lack of circulatory rest is underestimated. Lack of circulatory rest has been documented in the course of measurements by physicians as the so-called "white-coat-effect", inter alia, and is known.

The object of the invention is based on making available a blood pressure measuring method, or a sphygmomanometer, of the type mentioned at the outset, by means of which a user, in particular a layman, can perform dependable blood pressure measurements with as little effort as possible.

This object is attained by means of the characteristics of claim 1 or of claim 14.

In accordance with the method it has therefore been

provided that in the course of determining the individual pulse oscillogram an analysis regarding hemodynamic stability is furthermore performed, wherein at least one hemodynamic parameter, and/or at least one other physiological parameter which correlates with the hemodynamic parameter, are evaluated in respect to chronological changes, and that assessment criteria for the presence of hemodynamic stability are obtained from the analysis, by means of which the determination of the blood pressure value or the determined blood pressure value are brought into correlation in such a way that it is ascertained whether the blood pressure value was obtained during hemodynamic stability, or that a corrected blood value is determined.

In connection with the sphygmomanometer it is provided that the arrangement evaluating furthermore has an assessment arrangement which is embodied in such a way that by means of it assessment criteria regarding the presence of hemodynamic stability are established during the determination of the individual pulse oscillogram, and that the display device is provided with an indicator of hemodynamic instability.

It is achieved with these measures that a user can determine without additional outlay, without prolonging the measuring time, as well as without additional device adjustments, if a blood pressure measurement had been performed during hemodynamic instability. In this connection the blood pressure values are displayed together with the indication of hemodynamic instability, so that for example specialists can also draw suitable conclusions. It is also conceivable that only the fact of an error effect is signaled, or that a repeat measurement is requested, or that such is automatically started.

A contribution to user friendliness is provided in that a warning indication is generated by means of the evaluation criteria if they deviate from preset or predeterminable threshold criteria, wherein the type of the deviation can also be preset.

An assessment of hemodynamic stability directly linked to the blood pressure measurement is advantageously achieved in such a way that the individual pulse oscillogram is subjected to an analysis regarding hemodynamic stability.

The fact that, prior to obtaining the assessment criteria, influential values of artifacts and/or arrhythmia are suppressed, contributes to the increase of the accuracy of the assessment criteria.

In detail, various steps for deriving the assessment criteria consist in that a time-dependent pulse period progression, and/or a pulse amplitude progression, and/or the pulse shape, are determined and analyzed from the pulse oscillogram, and that the assessment criteria from the pulse period progression, the pulse amplitude progression, the pulse shape, or from a combined evaluation are formed from at least two items of this base information, wherein particularly dependable assessment criteria are obtained if the basic information in an at least partial combination is included in the evaluation.

In this case advantageous embodiments consist in that pulse period lengths of at least a starting range and an end range of the pulse oscillogram are compared with each other, and that a deviation of the pulse period lengths of the starting range and the end range is made the basis for the assessment criteria, or the trend change of the pulse period progression is determined.

A value which is suitable for comparison with threshold value criteria consists in that the deviation of the lengths of the pulse period is calculated by means of the pulse oscillogram as the difference of the lengths of the periods of the starting range and the end range as a function of a mean pulse period length of the pulse oscillogram.

Further advantageous measures for assessing the hemodynamic stability consist in that the entire progression of all pulse periods in regard to their chronological change is determined, and this change is used as a measure for the hemodynamic stability, or in that the entire progression of the pulse-specific systolic times in regard to their changes over time is determined, and this change is used as a measure of the hemodynamic stability.

The dependability of the assessment criteria is improved in that an assessment of the constancy of the entire chronological pulse period progression in particular is included when forming the assessment criteria.

Advantageous measures for using the pulse amplitude progression for forming the assessment criteria consist in that a rise in the ascending branch of the envelope or a rise in its descending branch, or a plateau width around their maximum, or a combination of at least two of these characteristic values from the pulse amplitude progression is/are used as characteristic values for forming the assessment criteria.

The shape of the pulse(curve) can be evaluated in particular in such a way that the analysis of the pulse shape includes a determination of one or several rises at least at one point of an ascending and/or a descending pulse flank, and that a chronological change in the rise(s) at the

respective points or a ratio of the rises at least at two points of a pulse is checked for different pulses as assessment criteria for the hemodynamic stability.

In this or a similar manner it is also possible to determine the change of the systolic time as assessment criteria for hemodynamic stability. It is possible here, for example, to make a meaningful base value in each the base area of a pulse and the top area of a pulse the basis for determining the length of the systole. This time is correlated with the ventricular contraction time of the heart.

If, for example, different meaningful characteristic values result from the pulse period progression and the pulse amplitude progression, the dependability for determining the hemodynamic stability can be increased in that the pulse period progression, the pulse amplitude progression and/or the pulse shape are weighted identically or differently, depending on their markedness, for forming the assessment criteria.

Alternatively or additionally, an embodiment option for assessing the hemodynamic stability consists in that, for assessing the hemodynamic stability, a breathing frequency signal, an electrocardiogram signal and/or a skin impedance measurement signal are determined as other, or added parameters, and evaluated in regard to a chronological change during the individual blood pressure measurement. In this connection it is provided, for example, that the breathing frequency signal is obtained from the analysis of the pulse oscillogram, or by means of an additional sensor arrangement.

An advantageous embodiment of the sphygmomanometer consists in that the assessment arrangement is designed for

detecting a pulse period progression, and/or a pulse amplitude progression, and/or pulse forms from the pulse oscillogram, and the formation of the assessment criteria from the pulse period progression, and/or the pulse amplitude progression, and/or a pulse form change.

An alternative or additional design option consists in that the assessment arrangement is designed for detecting at least one physiological additive factor correlated with a change of the hemodynamics which relates to, for example, a breathing frequency signal, an electrocardiogram signal and/or a skin impedance signal.

The mentioned measures can be provided, for example, in a sphygmomanometer at the upper arm or the wrist, wherein as a rule the evaluation and display device is arranged in a housing on the cuff, but can also be arranged removed or removable from the cuff. For example, the blood pressure values can be displayed together with the date and time and/or pulse frequency and stored in a suitable memory. Preset or predeterminable threshold values can be displayed, stored and monitored. Also, an interface for reading out detected data and/or reading in preset values or configurations of the evaluating device can be provided on the device.

The invention will be explained in greater detail in what follows by means of exemplary embodiments, making reference to the drawings. Shown are in:

Fig. 1, typical transitions of a systolic blood pressure progression and a diastolic blood pressure progression from areas of hemodynamic instability to stationary areas in a schematic representation,

Fig. 2, a schematic representation of a pulse

oscillogram with the envelope,

Fig. 3, a schematic representation for deriving assessment criteria for the hemodynamic stability from a pulse oscillogram,

Figs. 4A and 4B, envelopes of different pulse oscillograms with characteristic values in schematic representation,

Fig. 4C, a pulse curve progression, and

Fig. 5, a further schematic representation for the derivation of an assessment of the hemodynamic stability.

In a diagram, in which the blood pressure p_B has been applied over the time t, Fig. 1 represents transition times T_T of a systolic blood pressure progression p_{sys} and of a diastolic blood pressure progression p_{dia} from a stress value BW into a respective stationary range $Deltap_{sys}$ or $Deltap_{dia}$. The values $Deltap_{sys}$ and $Deltap_{dia}$ are derived from the physiological beat volume variation, as well as short-term vascular width changes in their effects on the blood pressure.

Circulatory rest exists if the systolic and diastolic blood pressure $Deltap_{sys}$ or $Deltap_{dia}$, as well as the heart frequency, of a patient move around respectively valid stationary values, i.e. not towards a resting value or away from a resting value. Circulatory rest is a prerequisite for the validity of internationally recognized threshold values of arterial blood pressure (WHO, 1999, as well as JNC7, 2003). These threshold values are used as target values when adjusting arterial blood pressure.

Systolic and diastolic blood pressure values change their values with the beat. This is the physiological short term variation of the arterial blood pressure. Typically, it

can amount systolically to up to 12 mmHg, and diastolically up to 8 mmHg. Besides these beat-related changes, however, the blood pressure of the resting, relaxed human is quasi stationary, i.e. changeable only very slowly.

Circulatory rest no longer exists if humans (must) undergo a physical load or (must) undergo physical stress. In these cases the systolic blood pressure rises as a rule, the diastolic blood pressure sinks slightly as a rule, but can also rise, and the pulse frequency rises regularly. Any organism adjusts in this way with a higher heartbeat volume to the stress situation which has arisen.

Following a physical or psychic stress, the organism requires a transition time T_T until circulatory rest again prevails. The transition time T_T depends on a number of factors, in particular extent and type of the stress, age, sex, training state, previous illness.

As a rule it is not possible to estimate the effects on the time of rest of the sum of the factors mentioned. For the layman in particular it is difficult to obtain information regarding the lack of circulatory rest. In many cases the transition time T_T is considerably underestimated in actuality, so that many blood pressure measurements do not yet take place during circulatory rest.

Typical times until relative circulatory rest has been achieved (± 10% of values at rest) are 2 min to 5 min. With older people and patients with previous illnesses, values of up to 15 min can occur. But the circulatory rest represents the most important error factor in the determination of the blood pressure at rest of a patient and is therefore automatically diagnosed by means of the measures described in greater detail in what follows in each individual blood

pressure measurement cycle (hemodynamic stability diagnosis = HSD). This is based on a pulse oscillogram PO, such as represented in Fig. 2 by way of example. Such a pulse oscillogram PO is always prepared in a known manner in the course of the measurement in connection with the method of oscillometric measurement applied here.

During a cycle of the oscillometric blood pressure measurement by means of the present hemodynamic stability diagnosis, a check is made whether or not the respective patient is in hemodynamic rest. The check for hemodynamic stability leads to a result indication which is preferably associated with the target values of systolic blood pressure value, diastolic blood pressure value and pulse frequency. In the course of this the hemodynamic stability is quantitatively determined, however, a binary indication, whether or not the stability is considered to be sufficient, is provided to the end user.

For determining the hemodynamic stability, the user strives not to perform any activities or device settings during or after the measurements. The measuring time of the blood pressure measurement is not prolonged by the hemodynamic stability diagnosis, because the diagnosis takes place in the same measuring cycle, and the subsequent signal analysis leads practically without delays to an indication of the final results.

The determination of the hemodynamic stability provides the result of the oscillometric blood pressure measurement with the additional information as to whether the required measurement conditions for determining the resting blood pressure had been met. If the rest requirements have not been met, the hemodynamic diagnosis identifies the obtained

measurements with a suitable indication as "measurements while circulatory rest is lacking".

With a pulse oscillogram, such as is represented by way of example in Fig. 2 and which represents the progression of the pulse pressure p_p over the time t, the amplitude of the individual pulses during the release of the cuff pressure increases to a maximum, which on the basis of physical laws is achieved when the cuff pressure corresponds to the mean arterial blood pressure (MAP). Subsequently the amplitude of the individual pulses decreases again. The amplitude progression is shown by the also represented envelope.

The systolic blood pressure therefore is reached in the rising portion of the envelope, for example at a time t_{sys}, and the diastolic blood pressure in the falling portion of the envelope, for example at a time t_{dia}. These times result from calibration constants preset in the devices and are derived from the pulse oscillogram. This applies to the systole and the diastole. However, even before the cuff releases the compressed artery again, the pressure pulses occurring on the heart side of the cuff have an effect on the cuff pressure (beat pulses), so that oscillation of the cuff pressure, and therefore also of the pulse oscillogram, becomes noticeable before the systolic blood pressure p_{sys} has been reached in the course of lowering the cuff pressure. This effect can also be used in the diagnosis of the hemodynamic stability.

For diagnosing the hemodynamic stability, in accordance with Fig. 3 and based on the pulse oscillogram obtained in a measuring stage 1, during a pulse period sequence analysis period 2 the pulse period progression is determined in an evaluation stage 2.2, and from this the pulse sequence in a

determination stage 2.3, and the constancy of the change of the pulse periods in the course of measuring in a detection stage 2.4. In the course of this, in the determination stage 2.3 the chronological pulse distance is advantageously measured in a starting time period $T_{initial}$, which lies before reaching the maximum t_{max}, and in a later time period $t_{terminal}$, and the difference of the pulse distances $T_{terminal} - T_{initial}$ is divided by a standardization value, for example the mean pulse distance T_{mittel}, in order to arrive at an assessment value R, which is compared with a preset or predeterminable threshold S in a decision stage 2.5. In this case the arithmetic mean value of all detected pulse distances of the pulse oscillogram PO, for example, can be made the basis of the mean pulse distance T_{mittel}.

Furthermore, a constancy evaluation is supplied to the decision stage 2.5 parallel with the assessment criteria R in the form of a pulse period change, which is performed in the detection stage 2.4. Then, in the decision stage 2.5 it is determined on the basis of preset or predeterminable criteria whether or not hemodynamic stability exists during the blood pressure measurement. It is already possible by means of this pulse period sequence analysis to form conclusions regarding the presence of hemodynamic stability, or the presence of stationary conditions, and a corresponding indication for the display can be generated. In order to obtain as large as possible a time difference for detecting the initial and later pulse distances $T_{initial}$ and $T_{terminal}$, and therefore an improved selectivity, it is advantageous to include the initial pulse distances $T_{initial}$ as early as possible, i.e. to include the pulse obtained prior to reaching the systolic pressure p_{sys} if possible, as mentioned

above. The later pulse distance $T_{terminal}$ should be detected during a later time period of the descending pulse oscillogram range which has a relation to the time of the diastolic pressure determination, if possible.

An analysis of the chronological progression of the pulse periods can be applied to all pulses within a measurement in that their chronological change is detected by means of a suitable statistical analysis - for example a progression analysis -.

A further statement regarding the presence of hemodynamic stability can be obtained by means of the evaluation of the pulse amplitudes, which are marked in particular by the envelope of the pulse oscillogram PO and represented for different cases in Figs. 4A and 4B. A theoretical envelope of a pulse oscillogram PO in an initial time period $T_{initial}$ is represented by way of example in Fig. 4A by a solid line. A dashed line shows the progression of the envelope at a later time period $T_{terminal}$. The different envelopes are part of statistical circulation conditions and show as characteristic values for example an ascending angle α, α' and a descending angle β, β', and/or (relative) plateau areas PL', PL".

An envelope resulting from measuring technology is represented in Fig. 4B, which is created as a cumulative curve because of the superimposition over the measuring time. It is possible to also derive appropriate characteristic values (α, β, PL) from the cumulative curve, which are a substantial function of hemodynamic stability. For example, it is possible to define the plateau length t_{PL} as a period of time in which the pulse pressure p_p lies no less than a preset percentile value (for example 10%) below the maximum.

For obtaining a suitable statement, the plateau length can be related to a further length of time during which the pulse pressure p_p does not lie less than a low preset percentile value (for example 90%) below the maximum (for example t_{90}), so that $R_{PL} = T_{PL} / T_{90}$ results as the characteristic value, for example.

Moreover, the ascent time and the descent time can be determined by a value V_{Base} related to the maximum for both flanks of the pulse oscillogram. The descent time T_N and the ascent time T_P result in this way. The two values can be placed in relation to each other, for example by means of a steepness index $S = T_N/T_P$. The steepness index S changes during hemodynamic instability.

The characteristic values in accordance with Figs. 4A and 4B can be used for characterizing the pulse amplitude progression and for drawing conclusions regarding the presence of hemodynamic stability from this.

Further assessment criteria for hemodynamic stability result from a pulse (curve) shape analysis by means of distinguishing characteristics which show, for example in accordance with Fig. 4C, a pulse curve progression p(t) over the time t. In the course of this the changes of steepness of ascending and/or descending pulse flanks during the measurement are for example determined. In the ascending pulse flank the rise is determined for a point xi $(A_{max} - A_{min}) + A_{min})$, wherein A_{max} is the maximum and A_{min} the minimum of the respective amplitude, and xi represents a value between zero and one, and the rise is expressed by the angle theta. In the descending pulse flank the rises for the points $delta_1$ $(A_{max} - A_{min}) + A_{min}$, as well as $delta_2$ $(A_{max} - - A_{min}) + A_{min}$ are calculated, wherein $delta_1$ and $delta_2$ are also values between

zero and one and the rises are expressed by the angles ny_1 and ny_2. Now hemodynamic changes can be detected by means of chronological changes of the rises theta, ny_1 and ny_2, so that the drawing of conclusions regarding the hemodynamic stability is made possible. In particular, the relationships of ny_1/theta, as well as ny_2/theta, are of diagnostic interest.

A change in the systole length can also be determined in a corresponding or similar manner, for example between a characteristic base value and a peak value defined in the area of the maximum. However, the entire progress of the pulse-specific systole time can be subjected to an analysis, for example a statistical trend analysis. The systole length can be used for assessment criteria.

In order to obtain the highest possible dependability for the formation of assessment criteria, regardless of whether hemodynamic stability exists during the blood pressure measurement, at least two of the evaluations, the pulse period sequence analysis in accordance with Fig. 3, the pulse amplitude analysis and the pulse shape analysis in combination with each other, can be observed together, as schematically represented in Fig. 5.

In accordance with Fig. 5, starting with the pulse oscillogram PO obtained in the measuring stage 1, the pulse period sequence analysis 2, the pulse amplitude progression analysis 3 and the pulse shape analysis 6 are performed in parallel, and both results are calculated together in a linkage stage 4, in order to form assessment criteria in an assessment stage 5 whether or not hemodynamic stability prevails. Depending on the characteristic markedness of the pulse period sequence analysis 2, the pulse amplitude

progression analysis 3 and/or the pulse shape analysis 6, different weightings $kappa_1$, $kappa_2$, $kappa_3$ of these analyses can be performed prior to or during the linkage stage 4 or in the assessment stage 5 for forming the assessment criteria wherein, for example, also a combination of only two of these analyses, or the values of the statements obtained from them, can be linked with each other. The result as to whether or not hemodynamic stability exists is then used for the optical and/or acoustic display, or the automatic performance of a repeat measurement wherein, in case of non-existent hemodynamic stability, an appropriate warning display or indication of the blood pressure values takes place. An embodiment of the blood pressure measuring method or the device can be realized in which the result of the hemodynamic stability analysis is used for correcting the blood pressure values.

Preferably the mentioned method steps or process stages for assessing the hemodynamic stability are realized by means of software through suitable programs in a micro-controller of an evaluating device of the sphygmomanometer. Here, the analysis of the pulse oscillogram for assessing the hemodynamic stability can be performed within a time frame and/or frequency range (spectral analysis). To the extent it is useful, it is possible here to provide suitable peripheral components for also controlling the display correspondingly, if desired for storing suitable values, or also for controlling an interface for input/output.

A selection of parameter sets can also be provided in the evaluating device, for example for automatically recognizing the patient cuffs, or to take other data into consideration. It is then possible on the basis of the

parameter sets to select individually matched programs in order to perform an appropriately refined diagnosis of the hemodynamic stability.

Based on characteristic properties of the pulse period progression and/or the pulse amplitude progression, it is also conceivable to detect influential values other than the hemodynamic instability as the effective causes of erroneous measured values.

In a further exemplary embodiment it is provided during the measurement as to whether or not hemodynamic stability exists that, alternatively or additionally to the above described analysis of the individual pulse oscillogram PO, one or several physiologically additive or further parameters are detected, which correlate with a chronological change of the hemodynamics. Such secondary parameters are, for example, the breathing modulation or breathing frequency, an electrocardiogram signal, or a skin impedance signal, which changes because of varying the stretching during breathing, or the moisture conditions. In this case the breathing modulation can be detected, for example, in the course of analyzing the pulse oscillogram PO prepared during the blood pressure measurement, or by means of an additional sensor device. Electrodes can be arranged on the cuff of the sphygmomanometer for obtaining the electrocardiogram signal, while a counter-electrode is separately provided. By means of a connection to the sphygmomanometer, in particular to its evaluating device, it is possible to obtain the secondary parameters by means of a justifiable outlay in the course of obtaining the assessment criteria of the hemodynamic stability. In a similar manner it is possible to determine the absolute pulse speed and to take it into consideration,

for example, by means of a separate pulse sensor.